

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/530,518 05/02/00 ARMSTRONG

L 106141

HM12/0723

EXAMINER

CLIFF & BERRIDGE
P O BOX 19928
ALEXANDRIA VA 22320

CHAUDHRY, M

ART UNIT	PAPER NUMBER
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1623

DATE MAILED:

07/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/530,518	ARMSTRONG ET AL.
	Examiner	Art Unit
	Mahreen Chaudhry	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 22-42 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 22-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 22-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 22 and 28, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 22-42, the phrase "X represents a group which limits the diffusion of the α -keto acid produced by the deamination of the cyclic amino acid" is unclear. The chemical group "X" is claimed functionally without recitation of any specific chemical structure and is thus indefinite. The specific chemical groups to which this claim is directed is unclear from a mere recitation of their characteristics. Additionally, it is unclear where and how the diffusion of the α -keto acid is limited. It is noted that the specification (p 5) recites that the diffusion of the α -keto acid is limited in hydrophilic media.

Regarding claims 23 and 31, the limitation, "X is chosen from hydrophobic groups" is unclear. The term "hydrophobic groups" is unduly broad and encompasses more than the specification could possibly support.

Regarding claim 25, the term "cation salt" is indefinite since it is unclear what specific cation salts may be utilized as revealing agents. The term "cation salt" is broad and encompasses more than the specification could possibly support. It is noted that the specification recites ammoniacal iron citrate as a revealing agent (p 12).

Regarding claims 39-40, "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 40, the "for example" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by each of U.S. Patent 4,937,352 issued to Voelter, U.S. Patent 4,507,230 issued to Tam et al., U.S. Patent 5,668,254 issued to Deghengi and U.S. Patent 5,173,434 issued to Morris et al. Voelter discloses histidine derivatives including 3-propylhistidine, 3-isopropylhistidine, 3-butylhistidine, 3-cyclopropylhistidine, 3-cyclopentylhistidine and 3-benzylhistidine which are all encompassed by the general formula recited in the claims (Column 11, Lines 25-33). Tam et al. disclose the

compound 3-benzyltyrosine which is also included by the general formula recited in the claims (Column 11, Line 3). Deghengi discloses 2-methyl tryptophan which is also included by general formula I (Column 4, Lines 37-41). In addition, Morris et al. disclose p-nitrophenylalanine which is also encompassed by formula recited in claims 30-31.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 22-23, 25-29 and 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,173,434 issued to Morris et al. in view of U.S. Patent 3,725,203 issued to Sellers. Morris et al. disclose a method for the identification of Proteus bacteria by the ability of these bacteria to deaminate L-amino acids to α-keto acids (Column 13, Lines 1-20). Morris et al. teach that the amino acid derivative p-nitrophenylalanine is utilized as the substrate to produce p-nitrophenylpyruvic acid which is detected by the appearance of brown color after the addition of NaOH (Column 13, Lines 11-15). Morris et al. teaches that an inoculum containing a bacterial isolate is added to a medium containing dimethyl coumarin and p-nitrophenylalanine (Column 13, Lines 22-40).

Morris et al. do not expressly disclose that the amino acid detecting agent is present in a culture medium. However, the identification of proteus bacteria by the addition of amino acid detecting agents to culture media is well-known. Sellers discloses that utilization of

phenylalanine or tryptophan in culture permits identification of proteus bacteria by the production of α -keto acid by deaminase activity (Column 3, Lines 13-18). Sellers teaches that the bacteria are incubated with phenylalanine and then treated with ferric chloride which reacts with phenylpyruvic acid to produce a green color (Column 3, Lines 13-18). Sellers discloses a culture medium containing L-tryptophan, L-phenylalanine, ferric ammonium citrate, brom cresol purple, brom thymol blue and agar (Column 3, Lines 41-50). Sellers teaches that L-tryptophan may be added in an amount sufficient to produce a detectable reaction, specifically in an amount between 1 and 5 g/l (Column 4, Lines 6-18).

Since bacterial deaminase activity results in the production of a detectable α -keto acid from both L-phenylalanine and the L-phenylalanine derivative, p-nitrophenylalanine, it would have been obvious to one having ordinary skill in the art to have substituted the L-phenylalanine in the culture medium taught by Sellers for the L-phenylalanine derivative, p-nitrophenylalanine, taught by Morris et al. It would additionally have been obvious that any amino acid or amino acid derivative capable of producing an α -keto acid could be utilized in a culture media for the detection of bacteria having deaminase activity since methods of detecting such α -keto acids are known in the art. Furthermore, it would have been obvious to have prepared these amino acid derivatives using methods known in the art. The point of novelty in the instant invention may be the substitution of the amino acid with a chemical group which limits the diffusion of the resulting α -keto acid in hydrophilic media thus permitting detection of a distinct colored product which does not diffuse through the media. However, the claims do not expressly recite what chemical groups limit the diffusion of the α -keto acid, how such diffusion is limited and the how such diffusion permits improved assay of deaminase activity.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

EP 171158A published by Beggs et al. disclose a culture test for deaminase positive bacteria by culturing microorganisms in the presence of L-tryptophan to produce indolepyruvic acid and treatment of the culture with metal ions and a fluorophore (abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc
July 18, 2001

R. Gitomer
RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200